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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,984	09/25/2000	Donn Nelton Rubingh	7070	3865

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EXAMINER

MOORE, WILLIAM W

ART UNIT PAPER NUMBER

1652

DATE MAILED: 10/22/2002

165

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/646,984	RUBINGH ET AL.	
	Examiner William W. Moore	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 June 2002.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2 and 11-28 is/are pending in the application.

4a) Of the above claim(s) 17,19,23,25 and 28 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1,2,11-16,18,20-22,24,26 and 27 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5 & 12.

4) Interview Summary (PTO-413) Paper No(s) _____.

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____.

DETAILED ACTION

Preliminary Amendments

Applicant's Preliminary Amendments A and B, Papers Nos. 3 and 8 filed respectively, September 16, 2000, and April 12, 2002, have been entered, the former canceling 5 claims 3-10 and introducing the new claims 11-28, and the latter providing a Sequence Listing in computer-readable and printed forms.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1, 2, 11-16, 18, 20-22, 24, 26 and 27, in Paper No. 13 filed June 24, 2002, is acknowledged. The traversal is on the 10 ground(s) that claims of Group I "consider deletions and substitutions at positions 70-84" just as claims of Group II "consider deletions and substitutions at positions 70-84". This is not found persuasive because no claim within Group I requires an amino acid substitution at any of the positions corresponding to positions 70-84 of the amino acid sequence of the mature subtilisin BPN'. Where the search for an amino acid substitution at any of the 15 positions 70-84 constitutes a separate and an additional burden beyond that required for a search for products meeting limitations of claims of Group I, the additional burden is an undue burden and the requirement is still deemed proper and is therefore made FINAL. Claims 17, 19, 23, 25 and 28 are withdrawn from further consideration as being drawn to a non-elected invention.

20 *Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. §112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

25 Claims 1, 2, 11-16, 18, 20-22, 24, 26 and 27 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 1 is indefinite in reciting, at lines 1-4, “[a] variant of a serine protease characterized by a modified amino acid sequence [. . . that] comprises a deletion of one or more of positions . . . corresponding to subtilisin BPN” because such a variant may be “characterized” in other fashions not described by the claim and because Applicant does not intend that any one of 15 positions correspond to the 275-amino acid sequence of subtilisin BPN’ but instead intends that amino acids – rather than positions – be deleted where the amino acids are present at positions that correspond to one or more of positions 5 70-84 of the amino acid sequence of subtilisin BPN’. Claims 12-14 similarly recite the ambiguous description, “deletion of one or more of positions . . . corresponding to subtilisin BPN”, and claims 2, 11-16, 18, 20-22, 24, 26 and 27 are included in this 10 rejection of claim 1 because they fail to clarify the ambiguities of claims 1 and 12-14 from which they depend.

Double Patenting

15 The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 20 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

25 A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

30 Claims 1, 2, 11-16, 18, 20, 21, 24 and 26 herein are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-15, 17 and 20 of copending Application serial No. 09/618,845. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the instant application describes “[a] variant of a serine protease . . . characterized by a modified amino acid sequence . . . compris[ing] a deletion

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of one of more of positions 70-84" and consequently may comprise further modifications, embracing the subject matters of claims 9-15, 17 and 20 of the copending application which describe "[a] serine protease variant comprising further amino acid sequence modifications in addition to a deletion of one or more of the amino acids at positions 70-84". The conflicting claims thus describe common subject matters that, while they are not identical, are coextensive.

5 This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10 *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

15 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20 This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. §103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. §103(c) and potential 35 U.S.C. §§102(e), (f) or (g) prior art under 35 U.S.C. §103(a).

25 Claims 1, 2, 11-16, 18, 20 and 22 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bryan et al., U.S. Patent No. 5,567,601, made of record herewith.

30 No pending claim currently requires that a subtilisin variant have a deletion of the amino acid at the position that corresponds to the subtilisin BPN' position 84. Bryan et al. do not directly anticipate the subject matter of the claims herein because claim 1 expressly excludes the most preferred amino acid deletion disclosed by Bryan et al. Yet Bryan et al. teach, at the close of col. 4, that their subtilisin BPN' mutants "will preferably comprise one or more" deletions "of the amino acids at positions 75-83" in addition to their "most preferred" deletion "of amino acids 75-83, of SEQUENCE ID NO:1." Bryan et al. teach 35 that such partial or total deletions will reduce the binding affinity for calcium ion at the primary calcium binding site of subtilisin BPN' and also teach, col. 11 at lines 36-41 and

claim 1, lines 7-15, that “one or more additional” deletions of amino acids at “the α -helix amino acid positions 70-74” may be included in a subtilisin mutant together with the deletions of one or more amino acids at the positions corresponding to positions 75-83 of subtilisin BPN’. Bryan et al. further teach the preparation of many of the stabilizing amino acid substitutions of claim 20 herein which they introduced to compensate for the reduced thermal stability of the subtilisin mutants lacking one or more of the native amino acids at positions corresponding to positions 70-83 of subtilisin BPN’ and that their subtilisin BPN’ mutants should be used in detergent compositions, which are cleaning compositions, designed for use with water having a low concentration of calcium ion. Thus it would have been obvious to one of ordinary skill in the art at the time the invention was made to follow the suggestions of Bryan et al. either to delete fewer of the amino acids among the positions corresponding to positions 75-83 of subtilisin BPN’ or to add to the most preferred deletion of Bryan et al. further deletions at the positions corresponding to positions 70-74 of subtilisin BPN’, as well as to formulate cleaning compositions comprising such variants. This is because such an artisan would have had a reasonable expectation that following the guidance of Bryan et al. would produce subtilisin variants, in addition to the “most preferred variant”, that are less dependent on calcium ion for stability yet have adequate stability by incorporating the series of stabilizing substitutions that Bryan et al. teach should be included when altering the calcium binding site region.

Claims 24 and 26 are rejected under 35 U.S.C. §103(a) as being unpatentable over Bryan et al. as applied to claims 1, 2, 11-16, 18 and 20 above, and further in view of Powell et al., U.S. Patent No. 6,060,546, made of record herewith.

The teachings of Bryan et al. discussed above are taken as before. Powell et al. teach the use of a serine protease in a personal care composition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a subtilisin variant that differed from the “most preferred variant” of Bryan et al. by following the

suggestions of Bryan et al. either to delete fewer of the amino acids among the positions corresponding to positions 75-83 of subtilisin BPN' or to add to the most preferred deletion of Bryan et al. further deletions at the positions corresponding to positions 70-74 of subtilisin BPN' and to substitute the resulting variant for the unmodified protease in a personal care composition of Powell et al. This is because one of ordinary skill in the art at that time would have had a reasonable expectation that any of the further subtilisin variants suggested by Bryan et al. would be suitable to incorporate in a personal care composition, particularly a composition destined for use with "soft" water or in a solution with a low calcium ion concentration such as the non-aqueous solution of Powell et al., because the artisan could anticipate that it would exhibit a stability comparable at least to the native protease taught by Powell et al.

Claim 21 is rejected under 35 U.S.C. §103(a) as being unpatentable over Bryan et al. as applied to claims 1, 2, 11-16, 18 and 20 above, and further in view of Arbige et al., EP 0 260 105, made of record with Applicant's Information Disclosure Statement.

The teachings of Bryan et al. discussed above are taken as before. Arbige et al. teach that introducing the amino acid substitution Y217L in subtilisin BPN', see page 6, line 46, through page 7, line 27, produces a mutant having increased stability and activity by comparison with the native subtilisin BPN' in non-aqueous solutions. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a subtilisin variant that differed from the "most preferred variant" of Bryan et al. by following the suggestions of Bryan et al. either to delete fewer of the amino acids among the positions corresponding to positions 75-83 of subtilisin BPN' or to add to the most preferred deletion of Bryan et al. further deletions at the positions corresponding to positions 70-74 of subtilisin BPN' and to substitute the substitution Y217L taught by Arbige et al. for the Y217K substitution taught by Bryan et al. This is because both Arbige et al. and Bryan et al. teach that their substitutions for the tyrosine at a position

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corresponding to position 217 in the amino acid sequence of subtilisin BPN' produces a more stable variant in solution conditions where calcium ion concentrations are low to non-existent and such an artisan at that time could anticipate that a Y217L-substituted calcium binding region deletion mutant would exhibit a stability comparable at least to a Y217K-
5 substituted calcium binding region deletion mutant.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 703.308.0583. The examiner can normally be reached between 7:00AM-5:30PM EST on Mondays and Wednesdays, between 7:00AM-1:30PM EST on Tuesdays and Thursdays, and between 8:30AM and 5:00PM EST on Fridays. The examiner's direct FAX telephone number is 703.746.3169. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached at 703.308.3804. Further fax phone numbers for the organization where this application or proceeding is assigned are 703.308.4242 for regular communications and 703.308.0294 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703.308.0196.

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William W. Moore
October 15, 2002



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